

REMARKS

The Office Action mailed June 24, 2003 (hereinafter the Office Action), has been received and reviewed. Claim 4 is pending in the application. However, claim 4 stands finally rejected. Applicants have herein amended claim 4 and have added new claims 5 through 9. Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

35 U.S.C. § 112 Rejection

Claim 4 is rejected in the Office Action under 35 U.S.C. § 112, second paragraph. In particular, it is asserted that the term "dosage form" contradicts the presence of a membrane in solution. The second paragraph of Section 112 requires that the specification of a patent application "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Applicants respectfully note the claim 4 has been amended and that, as amended, claim 4 particularly points out and distinctly claims subject matter that Applicants regard to be their invention. Therefore, Applicants respectfully request that the rejection of claim 4 be withdrawn.

35 U.S.C. § 102 Rejection

Claim 4 stands rejected under Section 102(b) as being anticipated by Buxton et al. However, in order for a reference to anticipate a claim under Section 102(b), that reference must expressly or inherently set forth each and every element recited in the rejected claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In other words, the identical invention must be shown in the cited reference in as complete detail as is contained in the rejected claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In this instance, Applicants respectfully submit that Buxton et al. does not teach or show the subject matter of claim 4 in as complete detail as is recited in the claim. Therefore, Applicants respectfully submit that Buxton et al. does not anticipate claim 4 under Section 102(b), and Applicants respectfully request

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that the rejection of claim 4 be withdrawn.

Claim 4, as it is amended, recites a method of fabricating a dosage form. The method of claim 4 comprises:

providing a core comprising a drug; providing a membrane forming composition comprising a polymer, an amphiphilic surfactant, and a single solvent, wherein the polymer, amphiphilic surfactant, and single solvent are selected such that both the polymer and amphiphilic surfactant are soluble in the single solvent to such a degree that only the single solvent is needed to provide the membrane forming composition; and forming a membrane over the core with the membrane forming composition.

Therefore, in order to anticipate claim 4, the teachings of Buxton et al. must identically set forth a method that calls for providing core comprising a drug, providing a membrane forming composition according to the specific limitations recited in claim 4, and forming a membrane over the core using such a composition. *See, Gechter v. Davidson*, 43 USPQ2d 1030 (Fed. Cir. 1997).

The disclosure provided by Buxton et al. teaches the formation of "spheroid cores" that are coated with a membrane material. The reference generally teaches that the membrane material may be formed using a polymer material, a surfactant, and, preferably, a plasticizer and an anti-tack agent. Buxton et al. further teaches that, among several other suitable materials, water insoluble celluloses may be used in the membrane composition and that suitable solvent systems for coating a membrane composition may include "water, dichloromethane, ethanol, methanol, isopropyl alcohol and acetone mixtures thereof, and the like." *See, Buxton et al.*, col. 2 and col. 3. However, the generalized teachings of Buxton et al. make no indication that materials and solvents disclosed therein could be brought together to form a membrane forming composition that includes a polymer, an amphiphilic surfactant, and a single solvent, wherein the polymer and amphiphilic surfactant are sufficiently soluble in the single solvent that only the single solvent is needed to provide the membrane forming composition. In fact, the Examples set forth in Buxton et al, which provide the only specific application of the generalized teachings found in the reference, teach away from a dosage form as recited in claim 4. Specifically, the Examples set forth in Buxton et al. disclose dosage forms that include membranes formed using a multi-solvent system (*i.e.*, dichloromethane/methanol). Therefore, Applicants respectfully submit that the teachings of Buxton et al. fail to identically set forth a method as recited in claim

4, and Applicants respectfully request that the rejection of claim 4 under Section 102(b) be withdrawn.

CONCLUSION

Claims 4 through 9 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Please direct any questions to the undersigned attorney at (650) 564-5106.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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